DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 14, 2015

Cordis Corporation
Mr. Babu Periasamy
Manager, Regulatory Affairs
6500 Paseo Padre Pkwy
Fremont, California 94555

Re: K143412
Trade/Device Name: ADROIT™ Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 12, 2014
Received: December 15, 2014

Dear Mr. Periasamy,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K143412

Device Name: ADROIT™ Guiding Catheter

Indications for Use:

The ***ADROIT™ Guiding Catheter*** is intended for use for intravascular introduction of interventional / diagnostic devices into the coronary or peripheral vascular systems.

Prescription Use __x____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA of 1990 and 21 CFR 807.92 in order to gain clearance to market the 5F ADROIT™ Guiding Catheter.

APPLICANT	Cordis Corporation Cordis Corporation, a Johnson & Johnson Company 6500 Paseo Padre Parkway Fremont, CA 94555 Tel.: 510-248-2464 Fax: 510-248-2533
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DATE PREPARED	January 14, 2015
TRADE NAME	ADROIT™ Guiding Catheter
COMMON NAME	Guiding Catheter
CLASSIFICATION NAME	Percutaneous catheter
DEVICE CLASSIFICATION	21 CFR §870.1250
PRODUCT CODES	DQY
PREDICATE DEVICE	Cordis 5F Vista Brite Tip® (VBT) Guiding Catheter, previously cleared under K000715.

SUBSTANTIALLY EQUIVALENT TO:

The Cordis 5F ADROIT™ Guiding Catheter is substantially equivalent to the Cordis 5F Vista Brite Tip® (VBT) Guiding Catheter, previously cleared under K000715.

DEVICE DESCRIPTION:

The 5F ADROIT™ Guiding Catheter features a 5F outer diameter, with a single through lumen of 0.058". The catheter body is reinforced with tightly wound stainless steel braid wire. The catheter body transitions to progressively lower durometers from the body to the distal tip, providing a gradual decrease in stiffness. The lumen is accessed via a polycarbonate luer hub. The 5F ADROIT™ Catheter is offered in an overall length of 100cm. A broad range of tip shapes are offered for specific procedures.

INTENDED USE:

The ***ADROIT™ Guiding Catheter*** is intended for use for intravascular introduction of interventional / diagnostic devices into the coronary or peripheral vascular systems.

TECHNOLOGICAL CHARACTERISTICS:

The 5F ADROIT™ Guiding Catheter incorporates a 0.058" single through lumen. A stainless steel braid is incorporated to the shaft construction to provide pushability, torqueablility and kink resistance. A PTFE liner provides a lubricious inner surface for the lumen for any diagnostic or interventional device that will be passed through the guide catheter. The outer surface of the catheter comprises progressively softer polymer materials from the hub to the distal tip so that the catheter has sufficient push and torque characteristics for vascular access, with a soft atraumatic distal tip.

PERFORMANCE DATA:

The following testing was performed to verify and validate the 5F ADROIT™ Guiding Catheter:

- Catheter ID
- Body and Tip Seal Strength
- Hydrostatic Pressure
- Hub Aspiration
- CSI Compatibility
- Kink Radius
- I-Torque
- Flexibility/ 3-Point Bend
- U-Torque
- Backup Support

Bench testing confirms that the 5F ADROIT™ Guiding Catheter can be used according to its intended use and in an equivalent manner to the predicate device.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The Cordis 5F ADROIT™ Guiding Catheter is substantially equivalent to the Cordis 5F Vista Brite Tip® (VBT) Guiding Catheter, previously cleared under K000715. The Adroit™ Guiding

Catheter is identical in design, intended use and performance characteristics of the VBT Guiding Catheter. A technological comparison and Design Verification and Validation testing demonstrate that the 5F ADROIT™ Guiding Catheter is substantially equivalent to the predicate device in the design, intended use and performance characteristics.